Aventis Pasteur

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00D-1543
Draft Guidance: 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms
[66 FR 48886, September 24, 2001]

20 December 2001

Dear Sir or Madam,

Aventis Pasteur would like to thank you for the opportunity to comment on the above-referenced Draft Guidance entitled "21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms." The document defines terms that will be used in other FDA guidance documents about Part 11. We offer the following comments/clarification for your consideration.

The definitions for seven out of fourteen terms defined in Section 3, "Definitions", are taken directly from 21 CFR Part 11 itself and are therefore redundant.

Definitions for other terms are either already present in other guidance publications (e.g., the definition of "Predicate Rule" is found in Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation") or could be effectively incorporated into those guidance documents.

The utility of maintaining this document as a stand-alone guidance is questionable.

On behalf of Aventis Pasteur, we appreciate the opportunity to comment on 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms and thank you for your consideration.

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Should you have any comments or questions, please address them directly to Maurice W. Harmon, Ph.D., Head, Regulatory Intelligence & Policy, by telephone at (570) 839-4398 or by facsimile at (570) 839-5529.

Sincerely,

Ricky D. Smith
Acting Site Head,
Regulatory Affairs
and Authorized Official

RDS/MWH/kh